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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,716	04/05/2001	Michael Karpusas	A062 US	4368

7590 08/21/2003
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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 08/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/826,716

Applicant(s)

KARPUSAS ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-19 and 21-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Status of Claims

1. Response to restriction requirement filed 5/19/2003 is acknowledged. Applicant elected, without traverse, Group V, claim 20.

Claims 1-33 are pending. Claims 1-19, 21-33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups. Cancellation of claims 1-19, 21-33 is requested.

Information Disclosure Statement

2. Applicants' Information Disclosure Statement filed 2/15/2002 has been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

Title, Abstract

3. The title and abstract of the invention are not descriptive. The title and abstract do not reflect the elected invention. A new title and abstract are required which are clearly indicative of the invention to which the elected claims are directed.

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Drawings

4. The drawings were approved.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim uses terms "α1β1 integrin" and "α1β1 integrin receptor". As α1β1 integrin is a receptor itself, the meaning of the "α1β1 integrin receptor" and its distinction from "α1β1 integrin" itself is not clear. Is it a receptor for a receptor?

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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6. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using $\alpha 1\beta 1$ integrin or a particular fragment thereof (as described in specification, page 16, last paragraph), does not reasonably provide enablement for using any fragment in the claimed screening method. The specification does not teach what core structure is required for "a fragment or homolog" to enable successful implementation of the claimed screening method. Broadly read, the claim reads on use of any single amino acid residue (used as "a fragment"), which obviously would produce results completely unrelated to binding to $\alpha 1\beta 1$ integrin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

7. Claim 21 is also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim is addressed, in part to use of " $\alpha 1\beta 1$ integrin receptor" (rather than $\alpha 1\beta 1$ integrin itself) in the claimed screening method. As neither the meaning of the term " $\alpha 1\beta 1$ integrin receptor" (see rejection under 35 U.S.C. 112, second paragraph, above), nor guidance

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on how to practice the invention with $\alpha 1\beta 1$ integrin receptor (rather than $\alpha 1\beta 1$ integrin itself) is present in the specification, the method as related to the use of $\alpha 1\beta 1$ integrin receptor was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 102 and 103.

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103[©] and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 20 is rejected under 35 U.S.C. 102(b) as anticipated by Holmvall, K. et al.(Database Caplus, DN 124:26891; Experimental Cell Research (1995), 221(2), 496-503) or Pfaff, M. et al. (Database Caplus, DN 121:248881; European Journal of Biochemistry (1994), 225(3), 975-84) or Kern et al. (Database Caplus, DN 119:89427; European Journal of Biochemistry (1993), 215(1), 151-9).

The claim is drawn to method for evaluating the ability of "a chemical entity" (i.e., any molecule) to associate (i.e., to interact in any way) with $\alpha 1\beta 1$ integrin, or fragment or homolog thereof. The method steps of obtaining data "related" to said association and analyzing the characteristics of the association read on any experimental or computational method which addresses interaction of $\alpha 1\beta 1$ integrin with a ligand. Performing "fitting operation" broadly reads on performing any interaction $\alpha 1\beta 1$ integrin with a putative ligand, as results of such interaction reflect whether the putative ligand "fits" $\alpha 1\beta 1$ integrin or not. Consequently the method as claimed is anticipated by the following exemplary references.

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Holmvall et al or Pfaff et al, or Kern et al., all describe employing experimental means to interact $\alpha 1\beta 1$ integrin with a putative ligand, such as collagen II or collagen IV, and analyzing results of this interaction, thus evaluating - using the language of instant claims - the ability of collagen (i.e., of a chemical entity) to interact with $\alpha 1\beta 1$ integrin.

It is Examiners position that all the elements of Applicant's invention with respect to the specified claims are instantly disclosed by the teaching of the reference(s) cited above.

9. Claim 20 is rejected under 35 U.S.C. 103(a) as obvious over Qu et al (Proc. Natl. Acad. Sci., 92, 10277-10281, 1995; reference BD).

Qu et al describe crystal structure of the I domain of complex of CD11a (i.e., of LFA-1 or $\alpha 1\beta 1$ integrin) which contains binding site for ICAMs . As identification of interaction of $\alpha 1\beta 1$ integrin with ICAMs and other $\alpha 1\beta 1$ integrin ligands is important for both understanding of mechanism of action of this physiologically important collagen receptor, and for screening for pharmacologically effective agonists/antagonists of $\alpha 1\beta 1$ integrin, it would be *prima facie* obvious to one skilled in the art, to use the crystal structure of Qu to identify interaction of $\alpha 1\beta 1$ integrin with its ligands.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

August 19, 2003

mlb

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Michael Borin', with a long horizontal stroke extending to the right.